REMARKS

Claim 1 has been amended, and claims 3, 4 and 6 have been cancelled. Therefore, claims 1, 2, 5, and 7-11 remain pending in the application.

I. Summary of Office Action

The drawings were objected to because the opto-microelectronic device" was not shown in the drawings, but is recited in the claims. Consequently, claims 3, 4, and 6 which refer to such element have been cancelled.

The specification was objected to because the Office asserted that the abstract contained "legalese". While the applicant does not understand precisely what "legalese" the Office is referring to, the abstract has been amended for clarification and brevity.

Claims 1 and 2 were rejected under 35 U.S.C. 102(b) as being anticipated by Tuke et al. (US 5,800,438).

Claims 3-6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuke in view of Muhs (US 5,701,370).

Claims 7 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuke in view of Ishizuka (US 6,716,043).

Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuke in view of Ishizuka, and further in view of Weismann (US 3,722,100).

Claims 10 and 11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuke in view of Ishizuka and Weisman, and further in view of Muhs.

All of the above claims rejections are respectfully traversed for the following reasons.

II. Arguments in favor of allowance over cited prior art

A. Differences between Tuke (US 5,800,438) and claims 1 and 2

With respect to claims 1 and 2, the Office states that Tuke discloses a dynamic spacer for measuring the flexion and extension gaps during knee arthroplasty having parallel planar members that engage tissue surfaces and that the spacer is used for measuring distances between first and said planar members.

In response, Tuke discloses a device that must be removed and reinserted during the arthroplasty procedure in order to obtain the necessary measurements. That device has a hand operable means arranged to cause movement of the second paddle flange to enable determination of the size of the flexion gap **or** the extension gap; it allows the surgeon to compare the size of the flexion **or** extension gap being checked with the flexion or extension gap that was checked in the previous maneuver with the device (Col.4 lines 6-15; col. 5 lines 11-17; col.10 lines 48-54). The specification explains that the surgeon must release the tool from the joint, while leaving the knob in the same position at which the flexion gap was displayed during the first measurement. The surgeon must then move the knee into full extension and **reinsert** the tool into the extension gap (Col. 9 lines 14-21).

In contrast, applicant does not claim a device that requires removal and reinsertion. Once the dynamic spacer is inserted, it can measure both the flexion and extension gaps. This is advantageous for two reasons. First, the dynamic spacer applies tension to the soft tissue without relying on the surgeon to repeatedly distract the knee in flexion and extension. Second, it minimizes the possibility that either additional cuts to the distal femoral bone will be required to increase the gap or that the distal femoral surface will require packing with bone cement because the gap is too large.

Tuke is further distinguishable because it claims a device where most components remain external to the knee during the arthroscopic procedure. The stainless steel central body, stainless

steel column, hand operable means (lever arm and handle), coil spring, ratchet and pawl, etc. are all bulky outside components that can block the soft tissue of the knee and prevent precise measurements of the flexion and extension gaps. The dynamic spacer of claim 1 does not have any cumbersome external components. It is more compact and it can more accurately measure the flexion and extension gaps.

For example, if the surgeon wants to measure the gap and the tension at 90 degrees using Tuke, he would need to place the Tuke instrument in at 90 degrees and tension the device, then measure the tension and the gap. After doing so, the surgeon has to remove the instrument and move the knee to perhaps 60 degrees or 0 degrees, apply the same tension, and then take the same measurement again. In contrast, the dynamic spacer of claim 1 stays in the knee and reads the distance, and it applies tension throughout the range of motion, thus allowing the surgeon to compare values without removing the surgical instrumentation during the surgery. The fact that the present invention is internal allows one to measure the true gap and tension more precisely, because the tension is done within the knee, as opposed to externally to the knee. In the case of Tuke's device, the measurement will not be accurate, because the tendons and soft tissue around the knee will push on the Tuke's instrumentation. Any devices, such as Tuke's, which measure from outside of the joint make the application difficult and inaccurate, because there is tension on the skin and on the tendons around the knee. If the entire instrumentation is inside, such as in the case of the present invention, this will allow better measurement and better assessment, because the device does not have to be removed and applied at a different angle of knee flexion. It can be kept in place, and the knee can be moved throughout range of motion measuring the gap in sequential manner.

The other main difference between Tuke and the present invention is that Tuke considers the knee as one unit, and it loads and measures both compartments using the same tensioner and measuring device. The present invention divides the knee into two compartments, medial and lateral, so each compartment of the knee is tensioned and measured independently. Studies have shown that those two compartments are different and that the tension is different, i.e. the gap is not the same in the medial and lateral compartment throughout the range of motion. Thus, the space between them and the tension varies thoughout the range of motion, and each compartment behaves differently. Tuke's device only reports the gap as being between the femurs and the tibia as one value. In the present invention, the inventors are placing separate two chambers, one medial and one lateral. These chambers apply the pressure from inside and also measure the value from inside, allowing the surgeon to treat each compartment independently.

Because the Tuke reference fails to disclose key elements of the applicants' invention, claim 1 should be regarded as both novel and nonobvious in comparison to the cited prior art. Inasmuch as the remaining dependent claims 2, 6, and 7-11 further define the invention over the cited art, those claims should likewise be allowable.

B. The remaining claims

Claims 3, 4, 5, and 6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuke in view of U.S. patent No. 5,701,370 to Muhs. The Office takes the position that Muhs teaches measuring angulation of genuflexion of the knee with an optoelectronic device that has digital output means. Muhs discloses a device that can be placed or worn on the human body at various locations, i.e, an external device. (Col. 2 lines 52-53). Muhs explains that the device is worn for monitoring and measuring joint articulation during activities such as exercise and

orthopedic rehabilitation (Col 4. lines 49-53). Hence, that device measures the extent of genuflexion of an intact joint (Col. 4 line 14).

Applicant's dynamic spacer is patentably distinct because it is surgically inserted into the knee joint. During arthroplastic surgery, it is placed between two bone surfaces that have been surgically cut to aid in balancing soft tissue around the knee. The dynamic spacer measures the gap between the surfaces of the proximal tibia and the distal femur [0012]. Furthermore, the means for measuring angulation in claims 5 and 6 refers to the rotational alignment of the distal femur[1] and not to the degree to which the knee is bent as in Muhs. [0011]. In view of these distinctions, a person of ordinary skill in this field would not be able to arrive at the device of claims 3-6 because Muhs simply does not attribute any significance to measuring a gap between the tibia or femur nor to the axis of femoral rotation.

Claims 7 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuke in view of U.S. patent No. 6,716,043 to Ishizuka. The Office contends that Tuke discloses the claimed invention except for the tensioning means comprising compressive coil springs and that Ishizuka teaches said tensioning means. In response, Tuke is patentably distinct from and does not disclose the claimed invention. Furthermore, Ishizuka discloses a spring connector, which is used to form a conductive circuit for electronic devices. Applicant asserts that Ishizuka is not reasonably pertinent to the problem with which the inventor is concerned because a person of ordinary skill in orthopedics and the human musculoskeletal systems, seeking to solve the

[1] One of skill in the art would define this axis as the angle substended by a line drawn from the center of the femoral head to the center of the knee and a line drawn from the center of the knee to the center of the talus; it is well known that by determining the femoral rotational axis, perfect symmetry in 90 flexion can be achieved..

problem of accurately measuring the flexion-extension gap during total knee arthroplasty, would not reasonably be expected to look to an electronic circuit connector.[2]

Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuke in view of U.S. patent No. 6,716,043 to Ishizuka and further in view of U.S. Patent No. 3,722,100 to Weismann. As explained in detail above, Tuke and Ishizuka fail to show what the Office has asserted, and Weismann only teaches a syringe-like device with a plunger and cylindrical housing that has a numerical scale. The cited references fail to disclose a key elements of the applicant's invention, and claim 9 should be regarded as both novel and nonobvious in comparison to the those references.

Claims 10 and 11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuke in view of Ishizuka and Weisman in further view of Muhs. In response, Tuke does not disclose key elements of applicant's invention for the reasons described above, i.e. Tuke's device has external components and it must be removed and reinserted. Ishizuka discloses a spring connecter used to form a conductive circuit for electronic devices; thus, it is not reasonably pertinent to applicant's invention. Muhs measures genuflexion of the knee as opposed to the gap between the surfaces of the proximal tibia and the distal femur. Finally, Weismann simply discloses a syringe-like devise that may have a series of markings or indicia on the barrel. The combination of the above cited art still fails to establish a prima facie case for obviousness, as that combination does not teach all of the elements of claims 10 or 11. Therefore, claims 10 and 11 should also be allowable.

III. Conclusion

For the reasons expressed herein, the applicant respectfully requests that a Notice of Allowance be issued in this case. If the Office believes that there remain any impediments to

[2] See *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992).

such a Notice of Allowance, the undersigned would welcome a telephone call to resolve such issues as quickly as possible.

Respectfully submitted:

ADAMS AND REESE LLP

/WJD/

Warner J. Delaune, Jr., Reg. No. 36,781
450 Laurel Street, Suite 1900
Baton Rouge, LA 70801
Tel: (225) 336-5200
Fax: (225) 336-5118
Email: warner.delaune@arlaw.com